

1-9-91

124472
MRID No.

112701
Shaughnessy No.

Data Evaluation Record

~~BRODIFACOU~~

Acute toxicity for freshwater fish

GUIDELINE NUMBER: 72-1 (c)

CITATION: Hill, R.W. 1978. Brodifacoum: Determination of the acute toxicity of the active ingredient to Rainbow trout *Salmo gairdneri*. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Report No. BL/B/1877. Study No. D606/A.

REASON FOR SUBMISSION:

FIFRA '88 Reregistration.

RESULTS-	Valid _____	Invalid _____	Supplemental <u>X</u>
GUIDELINE-	Satisfied _____	Partially Satisfied _____	Not Satisfied <u>X</u>

DISCUSSION: Change classification to:

Supplemental, $LC_{50} = 0.025$ mg/kg (0.0124- 0.0327, NOEL <0.0241 mg/kg.

The LC_{50} was calculated with two sets of measured concentrations that were done in two series. Since Brodifacoum degrades, the calculation based upon the nominal concentrations is not acceptable.

There were "On" and "Off" measurements of the concentration:

'ON' measured immediately after test concentration is prepared.

'OFF' measured 24 hours after preparation.

Because of the phrasing of these definitions, EEB infers that the chemical analysis was not done on aquarium water, but was done on the stock solutions instead. This is inappropriate because of the changes in the concentrations that may be brought about by the fishes' metabolism.

ICI never calculates the LC_{50} based upon measured concentrations, but it does offer a table that would allow the calculation to be made using the "OFF" data. The "OFF" data is more appropriate than the "ON" data, although, if the variation isn't too great, means could be used.

Little explanation is given for the two "series" of groups. "Series II" appears to have been designed to "fill-in" gaps in the range of concentrations used. The dates of the test (March 6 to 19) lead EEB to infer that the test were conducted separately then their results were combined in order to calculate the LC_{50} .

EEB has made it's calculations by using the "OFF" data and combining the two series. The study could be upgraded to "Core" by explaining the points that have been discussed or by recalculating the data.

REVIEWED BY:

James J. Goodyear
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Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: James J. Goodyear

Date: Jan 8, 1991

APPROVED BY:

Leslie W. Touart
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Signature: Leslie W. Touart

Date: 1-9-91

ENVIRONMENTAL FATE AND EFFECTS DIVISION
ECOLOGICAL EFFECTS BRANCH
List B Phase 4 - Response on Existing Studies Reviewed

CHEMICAL AI NAME: Brodifacoum
CHEMICAL NO.: 112701

CASE NO.: 2755

REVIEWER'S NAME: James J. Goodyear
TELEPHONE NUMBER: 703-557-7726
DATE: January 4, 1991

USE PATTERN(S): In and around buildings.

GUIDELINE NO.: 72-1 (c). Acute toxicity for freshwater fish (TG)

TITLE: Brodifacoum: Determination of the acute toxicity of the active ingredient to Rainbow trout *Salmo gairdneri*. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Report No. BL/B/1877. Study No. D606/A.

MRIDS AND DATES OF STUDIES REVIEWED: MRID 124472 (1978) in 92195-010 (1990).

MRIDS AND DATES OF FULLY ACCEPTABLE STUDIES: None.

COMMENTS: Supplemental, $LC_{50}=0.025$ mg/kg (0.024-0.027), NOEL <0.024.

The LC_{50} was calculated with two sets of measured concentrations that were done in two series. Since Brodifacoum degrades, the calculation based upon the nominal concentrations is not acceptable. ICI doesn't calculate the LC_{50} based upon measured concentrations.

Little explanation is given for the two "series" of groups. "Series II" appears to have been designed to "fill-in" gaps in the range of concentrations used. The dates of the test (March 6 to 19) lead EEB to infer that the test were conducted separately then their results were combined in order to calculate the LC_{50} .

EEB has made it's calculations by using the data taken 24 hours after preparation and by combining the two series. The study could be upgraded to "Core" by explaining the points that have been discussed here or by recalculating the data.

VALIDATION SHEET

CRF # _____ PAGE _____ OF _____

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC #	CHEMICAL NAME	Validator:				Date:			
92.5%		brodifacoum	Larry Turner				4/14/79			
			Test Type:							
			Fish acute 96 hour LC ₅₀ Rainbow trout							
			Test ID.# ES-G1							

CITATION: Hill, R.W. 1978. Determination of the acute toxicity of PP 581 to rainbow trout (Salmo gairdneri). 17 p. Study conducted by Imperial Chemical Industries, Ltd. Brixham Laboratory. Submitted by ICI Americas, 10182-26; Acc. #234655, report 8I; 8/15/78.

RESULTS: Rainbow trout 96-hour LC₅₀ = 0.0528 mg/l (95% c.i. .047-.0599 mg/l). No mortality occurred at the lowest level of 0.032 mg/l; 100% mortality occurred at all dose levels of 0.075 mg/l and higher. Toxic symptoms included swimming at the surface, weakness, and darkened coloration. There was no effect noted on control fish. (See note at end for values based on measured concentrations.)

VALIDATION CATEGORY: Core

CATEGORY RATIONALE: Although two separate series of concentrations were tested at separate times, there appeared to be no intent to hide this fact. All other portions of the test seemed to meet or exceed guideline requirements, and a statistical analysis on the second series of concentrations yielded results that were essentially the same as for the two combined series.

CATEGORY REPAIRABILITY: NA

ABSTRACT: Rainbow trout were exposed for 96 hours to brodifacoum in two series of concentrations, as given below:

<u>Series</u>	<u>Date Started</u>	<u>Concentration</u>	<u>96-hour mortality</u>
I	3/6/78	.32	10/10
		.24	10/10
		.18	10/10
		.10	10/10
		.068	9/10
		FW control	0/10
		DMSO control	0/10
II	3/10/78	.28	10/10
		.155	10/10
		.075	10/10
		.042	1/10
		.032	0/10
		FW control	0/10

Because of degradation and/or precipitation of the test material, concentrations were renewed each day. Actual concentrations were measured before and after each renewal. Fresh concentrations were 75-100% of nominal, while concentrations just prior to renewal were 55-80% of nominal.

Procedures very closely followed Stephan (USEPA, 1975) except that the two different series were tested at different times and the water was $13^{\circ} \pm 1^{\circ}\text{C}$. Statistical analysis was conducted according to the Finney probit method, combining both of the series. When both series were run together on the EEB calculator, the data would not run, but when the five highest 100% mortality levels were excluded, a very comparable LC_{50} of 0.053 ppm was obtained, with an acceptable chi square. Series I could not be analyzed by itself because the lowest concentration produced 90% mortality. When Series II was analyzed by itself, according to Spearman-Kärber because of only one partial mortality level, an LC_{50} of 0.05 ppm was obtained.

NOTE: In accession 237703, additional information on this test was supplied. The LC_{50} values for 24, 48, 72, and 96 hours were calculated, apparently by probit analysis, based on (a) measured fresh concentrations, (b) measured concentrations just prior to renewal, and (c) mean values of the above two. These 96 hour values are given below:

Rainbow 96-hour LC_{50} = (a) .045 ppm, (b) 0.33 ppm, (c) .039 ppm

96 hour LC₅₀
 Finney probit
 brodifacoum 92.5%

Rainbow Trout 0.032
 0.
 10.

L. Turner
 4/14/79 0.042
 1.
 10.

0.068
 9.
 10.

0.075
 10.
 10.

0.1
 10.
 10.

13.469
 22.205
 1.186
 0.378

0.053
 0.047
 0.060

0.042
 0.036
 0.050

0.066
 0.057
 0.076

M
 YINT
 LW M
 CHI²

LD50
 LDCL
 UPCL

LD10
 LDCL
 UPCL

LD90
 LDCL
 UPCL

96-hour LC₅₀ - rainbow trout
 & Trimmed Spearman-Kärber
 brodifacoum 92.5%

0.032
 0.
 10.

L. Turner
 4/16/79

0.042
 1.
 10.

0.075
 10.
 10.

0.155
 10.
 10.

0.28
 10.
 10.

10.
 0.05
 0.05
 0.06

NTRM
 LC50
 LDCL
 UPCL

Series II doses only

61

combination of series I and II dose levels,
 dropping the 5 highest 100% mortality levels.